UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC LIABILITY LITIGATION	**MDL No. 2419** **Master Dkt. No. 1:13-md-2419 (FDS)**
THIS DOCUMENT RELATES TO: **All Actions**	

INSIGHT HEALTH CORP.'S OBJECTIONS TO AND MOTION TO QUASH THE PLAINTIFFS' STEERING COMMITTEE'S SUBPOENA

Comes now Insight Health Corp. ("IHC") and submits its Objections to Plaintiffs' Steering Committee's ("PSC") Subpoena to Produce Documents, Information, or Objects, or to Permit Inspection of Premises in a Civil Action. PSC's subpoena should be quashed or modified pursuant to Federal Rules of Civil Procedure 45 and 26. In the alternative, the Court should issue a protective order pursuant to Federal Rule of Civil Procedure 26(c).

For the reasons stated below, PSC's subpoena has the following deficiencies:

IHC is already a party to the MDL through the Joshua Mowles v. NECC, et. al., Case No. 1:13-10558 in this Court, accordingly a third-party subpoena *duces tecum* such as the one referenced above is improper and should be quashed.

PSC failed to properly serve the subpoena on IHC in violation of Federal Rule of Civil Procedure 45(b)(1).

The subpoena exceeds the limited scope of discovery approved by the Court.

The subpoena creates an undue burden and seeks irrelevant information in violation of Federal Rules of Civil Procedure 26(b) and 45.

The subpoena does not provide a reasonable time to comply in violation of Federal Rules of Civil Procedure 45(c)(3) and 34(b)(2)(A).

Background

On July 3, 2013, PSC e-mailed a scanned .pdf copy of an attorney-issued United States District Court for the District of Massachusetts Subpoena which was signed by Patrick T. Fennell of the firm Crandall & Katt, in Roanoke, Virginia, on July 2, 2013. See Exhibit 1 attached. The e-mail from Patrick T. Fennell contained a blank proof of service page, and "Exhibit A to Subpoena" which contained twenty-one (21) enumerated paragraphs describing various documents and electronic information that IHC was commanded to produce to be inspected, copied, or tested. This above-described Subpoena *duces tecum* scheduled IHC's production at Insight Health Corp., on July 23, 2013, at 9:00 a.m.[1] The e-mail from Mr. Fennell containing this PSC subpoena stated that he was attaching a document subpoena and was wondering if IHC's counsel would accept service. On July 6, 2013, counsel for IHC responded to Mr. Fennell's e-mail refusing to accept service.

Law and Argument

I. Failure to Issue Proper Service

PSC failed to properly serve the subpoena because they e-mailed it to counsel for IHC along with a request for counsel to accept service on behalf of the IHC which was rejected. Even, if service of a subpoena is a proper mechanism to obtain documents from a party defendant to the MDL, and IHC submits it is not, service on IHC did not occur.

II. PSC's Breach of the Court's Limitation of Discovery

A. PSC's Breach of the January, 2011 — November, 2012, Timeframe

On June 21, this Court entered two Orders titled: "Order Granting Plaintiffs Leave

[1] Presumably, PSC seeks the documents, information, or objects to be produced at IHC's Roanoke facility located on Franklin Road in Roanoke, Virginia, but that is unclear.

to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information" ("QPO")[2] and "Order on Central Enforcement of Subpoenas" ("Enforcement Order"). The QPO limited the time frame for PSC's subpoena requests, stating,

> The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC[3] solutions, medications or compounds from January, 2011 — November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and PSC reasonably determine necessary to the prosecution and resolution of these actions.[4]

However PSC's subpoena is for a more expansive timeframe than that contained in the QPO in one instance requesting that IHC provide documents and things for a five year period, and in several other instances for a two year period.[5]

B. PSC's Subpoena Attempts to Circumvent the Court's Requirement that Protected Health Information be Produced to a Vendor

Notwithstanding the PSC subpoena is invalid for reasons set forth above, assuming arguendo that IHC as a party could be subject to such a subpoena, PSC's subpoena also violates the Court's QPO by requesting IHC produce the documents directly to PSC. The Court clearly ruled that protected health information shall be produced only to a third-party Vendor.[6] PSC has prematurely subpoenaed the records of IHC, because the Vendor has apparently not even been retained by PSC.

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[2] See MDL No. 1:13-md-2419 (FDS).
[3] Id. at Doc. 192 at ¶¶1-3, 6, and 9 where New England Compounding Pharmacy, Inc., is also referred to as ("NECC").
[4] Id., at ¶2.
[5] PSC Subpoena "Exhibit A to Subpoena" ¶¶ 1, 3-7, 9 and tho the extent any other paragraphs request documets beyond the timeframe limitation of the QPO.
[6] See Supra, MDL No. 1:13-md-2419 (FDS), Doc. 192 at ¶3.

C. PSC Did Not Append the QPO to the Subpoenas

The Court ruled that its QPO order "shall be appended to the subpoenas."[7] In its rush to subpoena the records of IHC, PSC did not append the QPO to the subpoena served on IHC.[8]

III. PSC's Subpoena is an Undue Burden

When applied to the subpoena served upon IHC, the factors weigh overwhelmingly in favor of quashing the subpoena.

First, as previously stated, the only documents that are relevant to the MDL and possessed by IHC are the protected health records of the plaintiffs in the MDL that received treatment from IHC that contained MPA from the effected lots. Many of the documents requested by PSC are easily accessible from other, more appropriate, sources. PSC requested numerous documents regarding the recall of NECP's ("NECC") medications that can be easily obtained from the FDA, CDC, or Virginia Department of Health. Furthermore, the overwhelming majority of the documents requested can be easily produced by NECC, an actual party to the MDL. The fact that NECC's bankruptcy case and federal investigation may somehow delay discovery from NECC is no reason to burden Virginia healthcare providers. The overbreadth of PSC's twenty-one (21) enumerated paragraphs describing various documents and electronic information that IHC is purportedly being commanded to produce to be inspected, copied, or tested, is not only improper but is a clear burden. A sampling of PSC's overly broad, unduly burdensome, and irrelevant requests include:

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[7] Id. at ¶15.
[8] PSC Subpoena. – attached hereto as Exhibit 1.

2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth and identification of product administered.

10. Any and all documents and/or ESI reflecting or containing information obtained by or communicated to Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, [sic] state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purposes.

IV. PSC Failed to Provide IHC with a Reasonable Period of Time to Comply

PSC has failed to provide IHC a reasonable period of time to comply with its subpoena for documents. Even if this were a Rule 34 request, per Fed. R. Civ. P. 34(b)(2)(A), a respondent would still get 30 days to comply with a request for production. PSC only provided IHC 20 days to respond to its Subpoena. Therefore, pursuant to Fed. R.Civ. P. 45(c)(3)(A)(i), the Court must quash or modify the subpoena. However, even if PSC provided IHC with 30 days to comply, 30 days is far too short of a timeframe to comply with the overbroad and unduly burdensome requests propounded by IHC.

By identifying specific deficiencies in specific paragraphs, IHC does not waive the right to object to other paragraphs, particularly those which request "Any and all

documents and ESI reflecting and/or related to..." which are facially overbroad and unduly burdensome.

V. Conclusion

For the reasons stated herein, IHC requests the Court quash or modify the subpoena in accord with IHC's objections.

COUNSEL FOR IHC REQUESTS TO BE HEARD ON THIS OPPOSITION TELEPHONICALLY.

Dated this 15th day of July, 2013.

Respectfully submitted,

BONNER KIERNAN TREBACH & CROCIATA, LLP

/S/ Clinton R. Shaw, Jr., Esq.

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Counsel for Defendant Insight Health Corp.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I caused the foregoing Objections to and Motion to Quash Plaintiffs' Steering Committee's ("PSC") Subpoena to Produce Documents, was served via email on this 15th day of July, 2013 to:

Patrick T. Fennell, Esq.
Crandall & Katt
366 Elm Avenue, SW
Roanoke, VA 24016
P-540-342-2000
F-540-400-0616
E-mail PFennell@crandalllaw.com

/S/ Clinton R. Shaw, Jr., Esq.

Clinton R. Shaw Jr.

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In re: New England Compounding Pharmacy, Inc.
Plaintiff
v.

Defendant

Civil Action No. MDL 1:13-md-02419

(If the action is pending in another district, state where:)

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Insight Health Corp.

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material: See Exhbit A

Place: Insight Health Corp.	Date and Time: 07/23/2013 9:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 07/02/2013

CLERK OF COURT

Signature of Clerk or Deputy Clerk

OR

Attorney's signature

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* Plaintiffs' Steering Committee, who issues or requests this subpoena, are:

Patrick T. Fennell, Crandall & Katt, 366 Elm Avenue, SW, Roanoke, Virginia 24016

EXHIBIT 1

Civil Action No. MDL 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

☐ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

☐ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)

(c) Protecting a Person Subject to a Subpoena.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

EXHIBIT A

Exhibit A to Subpoena

1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied).

2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for opthalmic solution (before and after any discounts applied).

5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the

foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

6. Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

7. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between Insight Health Corp. ("Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

8. Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

9. Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

11. Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

12. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

13. Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

14. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

15. Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

16. Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia – National Formulary, Chapter 797 (USP – NF General Chapter 797, entitled "Pharmaceutical Compounding – Sterile Preparations").

17. Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

18. Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

19. Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

20. Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

21. Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.